

Notice of Allowability

Application No.

10/523,454

Examiner

Allison M. Ford

Applicant(s)

BADER, AUGUSTINUS

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to telephonic interview of 20 December 2007.
2. ☒ The allowed claim(s) is/are 87-96,98,99 and 113-122.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 20071220.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Leon B. Lankford, Jr.
Primary Examiner
Art Unit 1651

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Jay Franklin on 20 December 2007.

The application has been amended as follows:

Please use the following version of the claims:

1-86. (CANCELED)

87. A method of forming an implantable tissue construct for replacement of a human body part, the method comprising the steps of:

- a) forming an inert material into a porous support structure having a predetermined shape and size corresponding to the shape and size of a human body part to be replaced, and which substantially maintains the shape and size of the human body part to be replaced;
- b) encapsulating the entire porous support structure with a boundary layer of cell-impermeable material, which substantially conforms to the predetermined shape and size of the porous support structure;
- c) introducing living cells into the porous support structure;
- d) promoting cell growth by introducing nutrients and oxygen to the living cells in said porous support structure;
- e) after completion of cell growth, removing the boundary layer; and

f) eliminating the porous support structure; thereby producing an implantable tissue construct having a shape and size corresponding to the human body part to be replaced.

88. The method according to claim 87, wherein the step f) of eliminating the porous support structure (1) comprises either mechanically removing or biologically degrading the support structure.

89. The method according to claim 87, wherein the inert material used to form the porous support structure is phosphate.

90. The method according to claim 87, wherein the cell-impermeable boundary layer (4) is a biological material or a synthetic material.

91. The method according to claim 90, wherein the cell-impermeable boundary layer (4) is a hydrogel material.

92. The method according to claim 87, wherein the cell-impermeable boundary layer material (4) is gas permeable.

93. The method according to claim 87, wherein the step b) of encapsulating the porous support structure with the cell-impermeable boundary layer material (4) comprises one of spraying the porous support structure with the cell-impermeable boundary layer material or dipping the porous support structure in a bath (3) of the cell-impermeable boundary layer material.

94. The method according to claim 87, further comprising, between steps a) and b), a step a') forming an

intermediate layer, between the porous support structure (1) and the boundary layer (4), from a material which remains unbound to the support structure (1) so that the intermediate layer facilitates removal of the boundary layer from the porous support structure.

95. The method according to claim 94, wherein the intermediate layer is a lipid layer.

96. A method of forming an implantable tissue construct for replacement for a human body part, the method comprising the steps of:

- a) forming an inert material into a porous support structure having a shape and size corresponding to the shape and size of a human body part to be replaced;

- b) enclosing the entire porous support structure within a contiguous boundary layer of cell-impermeable material;

- c) providing the porous support structure with at least one inlet;

- d) introducing living cells into the porous structure;

- e) promoting cell growth within the porous support structure, by introducing nutrients and oxygen to the living cells, so that the cells conform to the size and shape of the porous support structure; and

- f) removing the boundary layer; thereby producing an implantable tissue construct having a size and shape corresponding to the shape and size of the human body part to be replaced.

97. (CANCELED)

98. A method of forming an implantable tissue construct for replacement of a human body part, the method comprising the steps of:

a) forming an inert material into a porous support structure having a predetermined shape and size corresponding to the shape and size of a human body part to be replaced, and which substantially maintains the shape and size of the human body part to be replaced;

b) encapsulating the entire porous support structure with a boundary layer of cell-impermeable material, which substantially conforms to the predetermined shape and size of the porous support structure;

c) introducing living cells into the porous support structure;

d) promoting cell growth by introducing nutrients and oxygen to the living cells in said porous support structure;

e) after completion of cell growth, removing the boundary layer from the porous support material by mechanically detaching the boundary layer; and

f) solubilizing the porous support structure; thereby producing an implantable tissue construct having a shape and size corresponding to the human body part to be replaced.

99. A method of forming a plurality of implantable tissue constructs for replacement of human body parts, the method comprising the steps of:

a) forming an inert material into a plurality of porous support structures, each support structure having a predetermined shape and size corresponding to the shape and size of a human body part to be replaced, and which substantially maintain the shape and size of the human body part to be replaced;

b) completely encapsulating each of the porous support structures with a boundary layer of cell-impermeable material, which substantially conforms to the predetermined shape and size of each of the porous support structures;

c) introducing living cells into each of the porous support structures;

d) promoting cell growth in each of the porous support structures by introducing nutrients and oxygen to the living cells in each of said porous support structures; and

e) introducing a plurality of the porous support structures (1) into a nutrient solution to facilitate cell growth; and

f) after completion of cell growth, removing the boundary layer from each of the porous support structures; thereby producing a plurality of implantable tissue constructs each having a shape and size of the human body part to be replaced.

100-112. (CANCELLED)

113. The method according to claim 96, further comprising a step g) eliminating the porous support structure (1) by either mechanically removing, or biologically degrading the support structure.

114. The method according to claim 96, wherein the inert material used to form the porous support structure is phosphate.

115. The method according to claim 96, wherein the cell-impermeable boundary layer (4) is a biological material or a synthetic material.

116. The method according to claim 115, wherein the cell-impermeable boundary layer (4) is a hydrogel material.

117. The method according to claim 96, wherein the cell-impermeable boundary layer material (4) is gas permeable.

118. The method according to claim 96, wherein the step b) of enclosing the porous support structure with the cell-impermeable boundary layer material (4) comprises one of spraying the porous support structure with the cell-impermeable boundary layer material or dipping the porous support structure in a bath (3) of the cell-impermeable boundary layer material.

119. The method according to claim 96, further comprising, between steps a) and b), a step a') forming an intermediate layer, between the porous support structure (1) and the boundary layer (4), from a material which remains unbound to the support structure (1) so that the intermediate layer facilitates removal of the boundary layer from the porous support structure.

120. The method according to claim 119, wherein the intermediate layer is a lipid layer.

121. The method according to claim 96, further comprising a step g) eliminating the porous support structure from the implantable tissue construct.

122. The method according to claim 96, further comprising the step of removing the boundary layer (4) from the implantable tissue construct by one of:
mechanically detaching the boundary layer from the porous support structure, and
solubilizing the boundary layer.

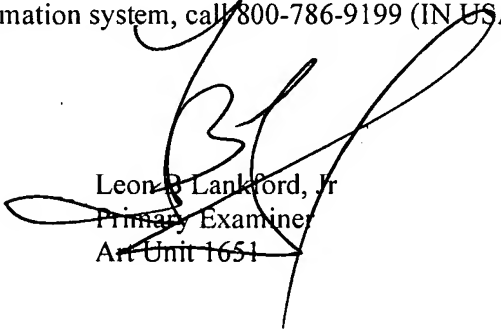
123. (CANCELLED)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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